U.S. Department of Health and Human Services
National Institutes of Health

National Institute of Allergy and Infectious Diseases (NIAID)

RFP-NIH-NIAID-DAIDS-06-06
Tri-Service AIDS Clinical Consortium Data Analysis and Coordinating Center (TACC/DACC)

1. OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE FOLLOWING WEBSITE FOR ANY SOLICITATION AMENDMENTS. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE. http://www.fedbizopps.gov/

2. SECTION A – SOLICITATION/CONTRACT FORM -- PURCHASE AUTHORITY: FAR 1.602-1

NOTE: The issuance of this solicitation does not commit the government to an award.

3. Issue Date:	**4. Due Date:**	**5. Small Bus. Set-Aside:**
January 21, 2005	April 21, 2005 **Time:** 3:00 PM , EST	[ ]Yes [x] No **8(a) Set-Aside:** [ ]Yes [x] No **NAICS:** 541710 (See Part IV, Section L.)

6. Just In Time:	**7. Number of Awards:**	**8. Technical Proposal Page Limits:**
[x] No [ ] Yes (See Part IV, Section L.)	[x] Only 1 Award [ ] Multiple Awards	Number of Copies: See Section J Page Limitations: 150 Pages Electronic File Size: 5 mega-bytes

9. Issued By:
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10. [X] **NIAID reserves the right to make awards without discussion.**

11. Options:
[X] No
[ ] Yes

12. Period of Performance:
5 years beginning on/about December 15, 2005

13. Primary Point of Contact:	**14. Secondary Point of Contact:**	**15. Protest Officer:**
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16. COLLECT CALLS WILL NOT BE ACCEPTED. FACSIMILE SUBMISSIONS ARE NOT ACCEPTABLE.

17. Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH-2043" (See SECTION J – Attachments)

18. DELIVERY ADDRESS INFORMATION

19. **Hand Delivery or Overnight Service:**	20. **U.S. Postal Service or an Express Delivery Service**
Lola Kellum Contract Specialist Contract Management Program, DEA NIAID, NIH 6700-B Rockledge Drive, Room 3214 Bethesda, MD 20817	Lola Kellum Contract Specialist Contract Management Program, DEA NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, MD 20892-7612

21. The **Official Point of Receipt** for the purpose of determining timely delivery is the address provided in Block 19, above. The original paper copy with original signatures is the official copy for recording timely receipt. If the original paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with HHSAR 352.215-70 entitled "Late Proposals and Revisions" located in this Solicitation. FACSIMILE SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.

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INTRODUCTION / BACKGROUND

Introduction

The Division of Acquired Immunodeficiency Syndrome (DAIDS), National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health, requests proposals to establish and manage a Data Analysis and Coordinating Center (DACC) for the Tri-Service AIDS Clinical Consortium (TACC), hereinafter referred to as the TACC DACC. The TACC is a multi-site, natural history study of HIV infection affecting primarily active duty U.S. military personnel and beneficiaries. The specific objective and scope of the TACC is to address the critical research questions on the natural and treated histories of HIV infection to minimize the adverse effects of HIV on the U.S. military community. The TACC collects medical, laboratory, and epidemiological data from the cohort to facilitate investigations of the biology and epidemiology of HIV transmission, factors affecting disease progression, effectiveness of therapy, and HIV treatment outcomes.

In 2002, the U.S. Military entered into an Interagency Agreement (IAA) that established a consortium between the Office of Clinical Research at NIAID and the military centers conducting research involving HIV-infected military members and their dependents. Under the IAA, a formal collaborative mechanism was developed, and the TACC was formed. A governing process for the network was established, consisting of a Coordinating Team (CT) composed of military investigators and NIAID scientists. The CT is responsible for the governance of the network, sets scientific priorities for research, and performs scientific review of research proposals. Specifically, the TACC CT makes recommendations on: all scientific, policy and organizational issues concerning development and implementation of research protocols; structure and membership of working groups; publications; access to data and interim data monitoring; and access to biological specimens. The TACC CT has overall responsibility for ensuring that protocols are conducted in keeping with high standards of scientific and programmatic achievement and that adequate mechanisms for systematic assessment of research quality are in place. In addition, an External Advisory Board (EAB) was established for the TACC. The EAB, composed of opinion leaders in HIV research from government and academia, was established for the TACC to provide additional scientific review of all proposed prospective studies for the TACC.

The services of a DACC are being sought to enhance the conduct of the TACC by providing scientific leadership and expertise in epidemiologic and biostatistical methods that optimize analyses of longitudinal cohort data. The DACC will provide technical expertise in data collection, data management and quality assurance to produce a valid and reliable database for analyses. The DACC will participate in TACC conference calls, assist in reviews of proposed concepts, and will be expected to play a dynamic role in interacting with the TACC sites and in helping to establish priorities and reasonable timelines for study activities, data analyses, and publications.

The NIAID anticipates awarding one contract for a period of five (5) years to perform the functions specified in the Statement of Work.

Background

HIV/AIDS in the U.S. Armed Services and the TACC

Routine HIV screening was initiated in the Armed Services in 1985 and since that time over 4,450 uniformed personnel have tested positive for HIV. In the U.S. the rate of HIV infection is lower in the military than in the general population, i.e., one to two people per 10,000 compared with 10 to 20 per 10,000, respectively. The three services perform HIV tests on different schedules, with the Air Force testing every 3 years and the Army and Navy testing every 2 years. It is estimated that over 95% of personnel in the armed services have been tested in the past two years. Since untreated HIV infection results in high morbidity and mortality, service men and women who tested HIV positive early in the epidemic tended to leave active duty within a few years of diagnosis. Today, HIV positive personnel identified by routine screening are much less likely to leave active duty. Only when individuals are unable to work do they receive medical discharge from active duty. Personnel who are medically discharged may still receive medical care at active duty care facilities.

Since homosexual contact and the use of illicit drugs are both cause for dismissal from the uniformed services, the collection of HIV risk behavior data in military personnel is extremely difficult. However, some carefully constructed surveys have found that the majority of HIV infections are due to homosexual behavior, and high risk heterosexual contact, in particular with commercial sex workers, is not uncommon. The military conducts frequent unannounced drug tests and the prevalence of illicit drug use among active duty personnel is very low.

Despite an active education program, members of the military reflect the risk profile of young U.S. adults. They are at risk for high levels of alcohol use, risky sexual contacts, and the resultant sexually transmitted infections, including HIV. The prevalence of high risk behaviors and the incidence of sexually transmitted diseases are even higher at times of deployment. Beginning in 2002, the U.S. military has had more personnel deployed abroad for longer periods than at any time since the 1990 Gulf War, potentially increasing the risk of HIV exposure among personnel.

Research and development efforts of the U.S. Military HIV Research Program (USMHRP) are aimed at minimizing the adverse effects of HIV on the U.S. military community. To meet this goal, the TACC focuses on activities within the U.S. Military HIV Program dealing with the biology and epidemiology of HIV transmission, and factors affecting disease progression, therapy effectiveness, and complications due to treatment. These efforts are conducted at the Tri-Service clinical research sites located at:

- Walter Reed Army Medical Center, Washington, D.C.
- Tripler Army Medical Center, Honolulu, Hawaii
- Brook Army Medical Center and Wilford Hall Medical Center (Air Force), San Antonio, Texas
- National Naval Medical Center, Bethesda, Maryland
- U.S. Naval Medical Center, San Diego, California
- Naval Medical Center, Portsmouth, Virginia

The cornerstone of the U.S. Military HIV Research Program is a longitudinal natural history study that provides a mechanism for the collection of comprehensive clinical, epidemiological and historical data in conjunction with laboratory analyses. The objectives of the natural history study are to:

(1) collect medical and epidemiological data on HIV-infected individuals who are Department of Defense (DoD) health care beneficiaries, with an emphasis on evaluating those who remain in active military service;
(2) study and develop clinical and laboratory surrogate markers for HIV progression;
(3) store serum, plasma, and cells as resources that may eventually provide answers to current and future HIV-related research questions; and
(4) provide an infrastructure of clinical research personnel, facilities and volunteers for the conduct of prospective research studies.

Data collected from the study have been important in defining prognostic factors for HIV, establishing new treatment paradigms, and defining the evolution of the U.S. HIV-1 epidemic in healthy young adults. Approximately 300 major publications have resulted from the work of the clinical program. The study design establishes systematic, standardized interval time points for the collection of the natural history data and phlebotomy samples. Several features make the military cohort unique, including:

(1) defined seroconversion intervals in many subjects due to military-wide routine screening;
(2) absence of social, educational, and economic barriers to health care in the military system;
(3) balance of racial demographics of the cohort participants; and
(4) open enrollment to include newly-identified HIV-positive individuals.

History of the TACC Cohort

To meet the primary mission of preventing HIV disease in military populations, two different protocols were developed in September 1988. These natural history studies collected medical and epidemiological data on HIV-infected individuals, principally among active duty personnel, but also among spouses in the DoD beneficiary pool. The Retrovirus 1 (RV1) protocol, "Natural History of HIV Infection and Disease in United States Military Beneficiaries," was designed to provide information based on longitudinal clinical and laboratory data.

The second protocol, RV2 "Core Protocol for HIV Developmental Diagnostics," used serum, plasma and cell samples to support basic research on HIV disease and to provide complementary information, such as the development of clinical and laboratory surrogate markers for HIV progression. In the late 1990s, radical changes in HIV treatment, morbidity, and mortality prompted a new study design, RV122 that consolidated the RV1 and RV2 protocols. During the RV1, RV2, and RV122 studies, 4,400 individuals were enrolled, of which 1,550 are alive and in active follow-up. The demographics of the cohort reflect the active duty military, since 43% are between 26 and 35 years of age, 90% are male, and all have a high school diploma or equivalent.

This is a unique cohort because the population is diagnosed early due to mandatory HIV testing of the military personnel. For 55% of the cohort, the time between the last HIV negative test and first positive test is less than one year, and the first CD4 cell count is greater than 400 cells/mm^3 for 75% of the cohort. Prompt enrollment soon after seroconversion has been instrumental in identifying early events and establishing their role(s) in disease progression and tracking the evolution of transmission of antiretroviral drug resistance. The cohort also is unique in its racial and ethnic diversity, and its lack of bias imposed by economic and social barriers to health care access. All HIV-positive active duty personnel receive Congressionally mandated visits every six months to the infectious disease specialty clinic for their service. RV122 capitalizes on these visits by enrolling and following consenting personnel. This ensures consistent time intervals for data and specimen collection and allows for the association of clinical status, CD4 counts, viral burden, clinical stage, and stored blood specimens at each visit. In addition, between the required six month visits, most personnel also receive regular HIV care at the same clinics. Thus, the RV122 database has access to interim clinic visit information on consenting participants.

The RV122 study is undergoing a second protocol revision in 2004. Further standardization of the protocol is planned, along with the implementation of data capture methods to collect data from other electronic databases in the U.S. military health system. The RV122 database will incorporate pharmacy data since 1996 and hospitalization records since 1992 from all consenting personnel. This will provide the RV122 study unprecedented data quality on therapy and outcomes among study participants.

These protocols provide the basis from which the interventional protocols in the Military HIV Research Program have originated. Interventional research in the military program ranges from studies to evaluate novel therapeutic drugs or regimens, to biodefense research, vaccination safety, and troop readiness of HIV-positive personnel. Clinical trials that recruit consenting participants from the RV122 cohort study have access to the wealth of longitudinal data collected in the cohort. These data are valuable for determining study eligibility and for comparing disease progression pre- and post-intervention. Study participants are experienced with clinical research, have at least a high school degree, are able to make informed decisions regarding their participation in clinical research, and are well prepared for full participation. Furthermore, the balanced racial and ethnic diversity of the cohort increases the ability to apply study results to populations not well served by other clinical trial networks.

SCOPE OF WORK

This contract will establish a Data Analysis and Coordinating Center (DACC) for the Tri-Service AIDS Clinical Consortium (TACC), hereinafter referred to as the TACC DACC. The TACC is a multi-site, natural history study of HIV infection affecting primarily active duty U.S. military personnel and beneficiaries. The specific objective and scope of the TACC are to address the critical research questions on the natural and treated histories of HIV infection to minimize the adverse effects of HIV on the U.S. military community. The TACC collects medical, laboratory, and epidemiological data from the cohort to facilitate investigations of the biology and epidemiology of HIV transmission and factors affecting disease progression, the effectiveness of therapy, and HIV treatment outcomes. The DACC will enhance the conduct of the TACC by providing scientific leadership and expertise in epidemiology and biostatistical methods that optimize analyses of longitudinal HIV cohort data and fully utilize the network of TACC clinical sites, laboratories and specimen repositories. A sound methodological approach to the measurement of disease incidence, prevalence, and progression, based on currently used or new surrogate markers, is necessary in several TACC studies where key events, such as time of HIV seroconversion, are unknown. Additionally, the DACC will provide technical expertise in data collection, data management and quality assurance to produce a valid and reliable database for analyses. The DACC will participate in TACC conference calls, assist in reviews of proposed concepts, and will interact with the TACC sites to guide the science of HIV research, and in helping to establish priorities and reasonable timelines for study activities, data analyses, and publications. The DACC will interact with the TACC sites and help establish, through its seat on the TACC Coordinating Team (CT), scientific priorities and reasonable timelines for study activities, data analyses, and publications.

STATEMENT OF WORK

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government under the terms of this contract, as needed to provide the statistical, technical, administrative and logistical expertise necessary to support the TACC in the design, implementation, and analyses of multi-site observational clinical studies. Specifically, the Contractor shall perform the following functions which are explained in detail in succeeding sections of this Statement of Work:

1. Collaboration with the TACC study sites and the TACC Coordinating Team (CT)
2. Initial Data Cleaning, Validation, and Quality Assurance Plan and Procedures
3. Ongoing Data Validation, Data Cleaning, and Quality Assurance
4. Security Requirements
5. Cohort Study Support, Training, and Communication
6. Consultation in Scientific Design and Analytic Strategies
7. Data Analysis for Retrospective, Prospective, and Collaborative Research
8. Clinical Trials Design and Analytic Support
9. Medical Reports and Presentations
10. Final Transition of Data and Documentation

1. **Collaboration with the TACC study sites and the TACC Research Coordinating Team (CT)**

A key requirement for the effective conduct of a complex study such as the TACC is the ability of the CT, the clinical study sites, the TACC investigators, and the DACC to work together in a cooperative and collegial fashion to accomplish scientific objectives. The objective is to have all TACC organizations function as a team. Accordingly, the Contractor shall establish effective lines of communications with DAIDS, the TACC CT and clinical site personnel and organizations. The TACC CT shall establish clear lines of authority and institute procedures for overcoming obstacles to effective communication within the DACC and among TACC investigators. The DACC will participate in the TACC conference calls and will facilitate communications between the TACC CT, the NIAID Project Officer and the clinical sites regarding TACC plans, procedures, scientific activities, and progress through use of the following mechanisms:

a. Prepare semi-annual statistical reports on the scientific progress advancing the knowledge and understanding of HIV infection through proposed concepts, approved investigations, data analyses, presentations, and publications using the TACC data.

b. Coordinate scheduled bimonthly conference calls for each of the scientific working groups and for the TACC CT. The agenda for each call will be pre-arranged by the TACC Principal Investigator or by the chair of each specific working group. Additional conference calls may be necessary for coordinating the scientific agenda, for protocol revisions, for planning meetings, and to address other research-related issues.

c. Participate with the TACC CT to plan, coordinate and schedule bi-annual Meetings.

d. Utilize electronic mail for quick interaction among TACC organizations.

e. Establish web portal communication among TACC organizations.

2. **Initial Data Cleaning, Validation, and Quality Assurance Plan and Procedures**

Data Cleaning and Quality Assurance of the TACC database will occur in two phases. Under the initial phase, the Contractor will receive raw data from the existing TACC HIV-1 Natural History database managed by the U.S. Military HIV Research Program (USMHRP). The Contractor shall develop and implement a TACC CT-approved plan to clean and perform quality assurance procedures on that data. The second and ongoing phase of data cleaning and validation is explained in paragraph 3., below. A validated dataset, summary files, and clear documentation of cleaning procedures and programming will be returned to the data center for the U.S. Military HIV Research Program (USMHRP) within 12 months of receipt of raw data. In order to secure and manage the database during the validation processes, the data shall reside on a multiprocessor server with adequate memory and RAM to support complex data manipulation and graphical applications as well as working directories for use by data center staff and TACC investigators. The file system structure shall provide an efficient means of organizing all components of the data center activities. Statistical software shall include the most recent version of Windows for networking, SAS/BASE, SAS/STAT, SAS/GRAPH, SAS/IML, SAS/AF, SAS/FSP, SPlus, and other programming capacity for processing, storage, retrieval, and multivariable analyses of longitudinal clinical, laboratory, and pharmaceutical data for more than 5,000 observations. The Contractor shall provide an off-site secured storage facility for system back-ups. The database and management system shall be established and fully functional within 12 months from the date of contract award. The database and data management system shall include:

a. a comprehensive timeline for data cleaning and validation of the existing TACC HIV-1 Natural History database;

b. strategies to ensure data security, back-ups, and continuity during quality assurance procedures and data analyses;

c. strategies for assessing quality assurance needs as well as retrieval and recovery of prior missing enrollee data;

d. a specimen inventory and monitoring system that links study personal identification numbers (PIN) to bar-coded specimens within the specimen repository and that follows the selection and use of various specimens for specific TACC CT-approved projects;

e. a schedule for review and revision of operational manuals to reflect database structure and revisions;

f. a review and appropriate revision of the existing protocol for the data capture process including schedules of electronic data capture and local or centralized direct data entry; and

g. a strategy and timeline for training local site staff on revisions to the data documentation and any changes to the data entry protocol.

3. **Ongoing Data Validation, Management, and Quality Assurance**

The subsequent phases of data cleaning and validation shall occur concurrent with and at the conclusion of each six-month study visit window. The Contractor shall receive raw data from the USMHRP datacenter in real time, so that final data validation can begin after the conclusion of the six month study visit window. The Contractor shall implement CT-approved cleaning and quality assurance procedures to establish a validated full dataset and summary files. Validated data and all documentation for cleaning and organization, including data dictionaries, will be returned to the USMHRP datacenter. Summary files will be provided to each TACC clinical center. The Contractor shall administer a system for electronic communication, such as a web site, that links TACC clinical site investigators, the NIAID Project Officer, and the CT to protected shared information. This system shall also provide limited public access in order to promote collaboration with other HIV researchers, scientists, and investigators.

The Contractor shall develop systems that provide for:

a. The storage, tracking, retrieval, processing, and transferring of validated clinical, laboratory, and mechanistic study data integrated at a central data management facility.

b. Evaluation and implementation, in collaboration with the USMHRP data group, of computerized study forms and systems for remote entry and secure transmission of participant data from clinical sites to the central data management facility.

c. Computerized validation and error-checking to evaluate and improve the accuracy, timeliness and completeness of data submitted by the clinical sites, including verification of the clinical and laboratory data used to determine that study participants have reached defined endpoints.

d. A study-wide quality assurance and monitoring system that performs range and error-checking of clinical, survey, and laboratory data from every six-month study visit window and evaluates reliability, validity, and completeness of the data. The Contractor shall document all quality assurance activities per TACC CT guidelines including data evaluations, data cleaning schedules and programs, and all data edit. This system shall be capable of producing reports and flagging anomalous and missing data. All documentation shall be available for annual audits as required by Federal regulations.

e. A dedicated computerized inventory and distribution system documenting requests for data and specimens and programming for all data retrievals and analyses.

f. A secure web site and web-based portal to provide electronic communication and promote information-sharing and collaboration among clinical study sites, the NIAID Project Officer, the CT and the DACC. Within this portal, the Contractor shall create and maintain a password-protected, organized, searchable library of each proposed concept and manuscript and documentation of subsequent reviews.

g. Summary data files for TACC researchers and the NIAID Project Officer based upon CT guidelines and a six-month study visit schedule.

h. Integration of the Contractor's information system(s) with the relevant components of the Division of AIDS (DAIDS) Enterprise System (DAIDS-ES), a comprehensive system that supports the business functions, management and oversight responsibilities of the DAIDS. The current components of the DAIDS-ES include an adverse event reporting system and a protocol management system. To achieve DAIDS-ES compatibility, DAIDS and its grantees and contractors will implement applications or data exchange mechanisms using DAIDS defined platform technology standards.

4. **Security Requirements**

The Contractor shall develop, implement, and maintain security requirements, including:

a. An Automated Information System (AIS) Security Profile, which, at a minimum, shall include:

1) the Continuity of Operations Plan (COOP), also known as the Contingency Plan.
2) the Risk Analysis (RA); and
3) the System's Security Plan (SSP);

b. The development and maintenance of an up-to-date COOP following the guidance in DHHS AISSP Handbook (http://irm.cit.nih.gov/policy/aissp.html). At a minimum, the COOP shall cover emergency operations, backup operations, and recovery plans to assure continuous operations of the system's facility. COOP testing shall be conducted and the results recorded at least every six months.

c. A log or record of the results from testing the COOP, any existing plans and progress reports for implementing additional security safeguards and controls, and the system access authorization list. The profile shall be kept current for review and potential inspection upon demand by NIH/DHHS authorized agents. Upon request, copies of specified profile documents shall be presented to NIH/DHHS for its own system's security reporting purposes.

d. The preparation and submission, for NIAID Project Officer approval, of an RA following the guidance given in DHHS AISSP Handbook (http://irm.cit.nih.gov/policy/aissp.html). The RA shall be maintained and updated every three years, or in advance of implementing major system modifications or enhancements.

e. The preparation and submission of an annual SSP, following the instruction in OMB Bulletin 90-08, for review and approval by the NIAID Project Officer and the NIH Information Systems Security Officer (ISSO) (http://irm.cit.nih.gov/itmra/omb90-08.html).

f. Plans, procedures, and a recommended schedule and budget for implementation of security safeguards required to satisfy the anticipated conditions of acquiring data from clinical and mechanistic and biomarker study sites. This includes data integrity and security during electronic transmission or during transit from the USMHRP data center or from sites to the TACC DACC. All participant identifiable data is subject to the Privacy Act and DHHS and HIPAA regulations.

g. Provision for labeling, storage, handling, and disposal of sensitive or controlled data, media, and output.

h. Specifications for a secure web site and web-based portal to provide electronic communication and collaboration linkages among clinical study sites, the NIAID Project Officer, the CT and the DACC.

5. **Cohort Study Support, Training and Communication**

The Contractor shall provide intellectual input to the TACC in establishing priorities and reasonable timelines for study activities, and shall collaborate with the CT, NIAID, and other scientists to facilitate the achievement of the TACC's research objectives. The Contractor shall maintain organized, complete, specific, feasible, and ethical study protocols and research initiatives that continue to advance the science of HIV infection through clinical trials and observational, population-based research and data analyses. Specifically, the Contractor shall:

a. Assess the various components of the operation and management of the clinical sites, including: site management, organization and utilization of the site staff; communication among clinical, technical and administrative staff; and the adequacy of site facilities and study equipment.

b. Coordinate the revision of existing TACC questionnaires as specified by the TACC CT to ensure that data collection addresses current research on HIV/AIDS. Advise in the development and conduct testing of new questionnaires for the TACC.

c. Prepare and update operations manuals and data collection forms and monitor and standardize procedures for all data collection activities.

d. Develop strategies to maintain quality control at each clinical site to assure uniform, standardized data collection. Provide standardized training for clinical site staff via conference calls and meetings.

e. Delineate specific instructions and requirements necessary for the appropriate implementation of study forms for data collection and monitoring of clinical site personnel;

f. Provide travel expenses for DACC personnel associated with group meetings with clinical site personnel, when necessary, to ensure appropriate training. [NOTE: Travel for site visits and training of site personnel is in addition to the expected travel to semi-annual TACC meetings and annual research meetings for reporting scientific achievements.]

g. Perform site visits in the first 18 months of the contract to each study site location (7 total) to observe, evaluate, and modify study procedures for efficiency, standardization, and accuracy of study procedures and data collection. After the first visit, subsequent visits will occur at least once per year per study site.

h. Perform subsequent annual site visits, or more frequently as deemed necessary by the TACC CT and NIAID Project Officer, for the purposes of training site staff and conducting a review of interview skills and procedures, specimen collection skills and procedures, data management, interim data monitoring, and final data analysis and interpretation.

i. Submit post-site visit reports to the TACC CT and the NIAID Project Officer within one (1) month of each site visit to ensure that needs identified during visits are rapidly addressed.

j. Provide written and verbal feedback to sites after the completion of a 6-month study visit for all areas of study monitoring, including recruitment and retention of study participants and completeness and validity and reliability of data.

k. Provide logistical services for arranging all bi-monthly conference calls and any additional conference calls required for working groups, CT, and other ad hoc committees or study-related groups.

l. Provide for the incorporation of statistical, clinical, technical and administrative expertise, and curtail or discontinue personnel and fiscal resources when necessary to accommodate changing scientific priorities and opportunities.

6. **Consultation in Scientific Design and Analytic Strategies**

The Contractor shall provide scientific leadership in epidemiology and biostatistics to TACC investigators in the development and review of cutting edge design and analytic approaches that fully utilize the network of TACC clinical sites, laboratories and specimen repositories. A sound methodological approach to the measurement of disease incidence, prevalence, and progression, based on currently used or new surrogate markers, shall be necessary in several TACC studies where key events, such as time of HIV seroconversion, are unknown. Specifically, the Contractor, in performing its role as the DACC, shall provide input into the development, review, and implementation of concepts and sub-studies by:

a. delineating research questions that can be addressed with study data, are a priority for the accomplishment of TACC scientific objectives, and advance the understanding of HIV infection;

b. selecting appropriate study populations and control or comparison groups to address the research questions;

c. developing inclusion and exclusion criteria;

d. defining clinical end-points and immune/surrogate markers;

e. selecting and developing alternative study designs and data analysis plans, including approaches for limited sample size, and delineating the compromises that must be made in the face of immutable circumstances (e.g., small sample size due to rarity of disease or procedure);

f. assessing the feasibility of accessing appropriate data for retrospective analyses and for recruiting and retaining adequate numbers of study participants for proposed sub-studies;

g. designing and developing study forms, including case report forms, and informed consent documents; and

h. assuring that the type, number and volume of participant samples required are available and consulting clinical sites on the appropriate collection, testing, storage and shipping of participant samples.

7. **Data Analysis for Retrospective, Prospective, and Collaborative Research**

The Contractor shall conduct data analyses for TACC CT-approved concepts and manuscripts. Scientific and analytic support shall include instances where the DACC representative is the lead author, the DACC supplies full analytic support, or the DACC ensures access to data for other TACC collaborators. In addition, the Contractor shall:

a. provide staff with expertise in the following:

(1) theoretical statistics;
(2) epidemiology;
(3) data modeling, particularly longitudinal data;
(4) methodologies in controlling for effects of yet optimizing repeated measures;
(5) marginal structural modeling;
(6) causal inference, including appropriate use of propensity scores and instrumental variables; and
(7) exploratory data analysis and robust methods in determining population and person-level effects;

b. develop *a priori* data analysis plans as well as plans for secondary analyses;

c. develop innovative statistical methods to address scientific questions posed by the TACC investigators in light of their focus on military readiness and clinical outcomes as well as scientific questions posed by approved non-military scientific collaborators;

d. perform epidemiologic and methodological analyses (as in a. above) and develop novel methodological approaches utilizing data from the TACC after approval by the TACC CT;

e. develop specific research databases to be used in proposed concepts;

f. identify statistical parameters substantiating the choice of statistical tests employed in the techniques and methodologies used to conduct data analyses;

g. maintain a tracking system to document the analytic progress and status of TACC research proposals;

h. maintain and distribute to all TACC investigators and the NIAID Project Officer, at semi-annual meetings, a list of all publications, manuscripts in progress and presentations using data from the TACC; and

i. make drafts of manuscripts available for review (electronically or in hard-copy) by the NIAID Project Officer at the time they are circulated to co-authors, and when the final manuscripts are submitted for publication.

8. **Clinical Trials Design and Analytic Support**

The Contractor shall support the conduct of clinical trials within the cohort through:

a. consultation with TACC clinical investigators and other TACC CT-approved research collaborators on protocol development with respect to scientific merit;

b. consultation with TACC clinical investigators and other TACC CT-approved research collaborators on feasibility of clinical trials implementation;

c. evaluation and documentation of eligibility of TACC participants for specific clinical trials;

d. the provision of clinical site training to implement the clinical trials protocols; and

e. coordination with the NIAID Office of Clinical Research which will secure Investigational Review Board approval (IRB) for TACC clinical trials and will hold the investigational new drug (IND) number for any new therapeutics.

9. **Medical Reports and Presentations**

The Contractor shall prepare and present semi-annual reports at the TACC CT and External Advisory Board meetings. These reports and presentations shall include results of data analyses, publications, findings of site visits, and recommendations for study procedures. The Contractor shall participate in the preparation of scientific abstracts and manuscripts for publication and presentation at scientific meetings. Such reports shall be approved by the TACC CT and the NIAID Project Officer before distribution and shall be of sufficiently high editorial quality as to require little, if any, additional editing by the NIAID Project Officer.

The Contractor shall submit all abstracts, manuscripts and reviews authored and/or co-authored by TACC investigators to the TACC CT and the NIAID Project Officer. The Contractor, the CT, and co-investigators are required to submit manuscripts to the NIAID Project Officer within two weeks of acceptance for publication so that an up-to-date summary of program accomplishments can be maintained. Publications or oral presentations of work performed under this contract are the responsibility of the Contractor and co-investigators and shall require appropriate acknowledgement of the US HIV Military Research Program and NIAID support.

10. **Final Transition of Data and Documentation**

The Contractor shall provide a Final Data Transition Plan six months prior to the completion date of the contract. The Contractor shall submit the written plan in draft to the NIAID Contracting Officer and NIAID Project Officer for review and approval to ensure an orderly transfer of this project to a subsequent contractor, if other than the incumbent, or to the Government. Upon review and comment on the draft plan by the NIAID Project Officer, the Contractor shall provide the plan in final form, incorporating the comments/changes of the NIAID Project Officer.

Should the responsibilities of the DACC be transferred either to a successor contractor or to the Government, the Contractor shall provide the following deliverables not later than the completion date of the contract:

a. a cleaned and edited public use data set, on media to be determined at the time of delivery by the NIAID Project Officer, and copies of all data management tools, including data documentation, data dictionaries, and data entry software and editing programs to allow reading and analysis of the data;

b. all computer programs used for reading, cleaning, manipulating, graphing, and analyzing TACC data and programs used for generating new datasets;

c. an audit trail of all raw data corrections, hard copies of the original data collected from study participants from all studies supported by this contract, and all logs and other records related to data collection, entry, editing, analysis and transfer;

d. delivery of final summaries of analyses performed by the Contractor during the contract period;

e. transfer of all electronic files in a format that is well documented to a location specified by the TACC CT and NIAID Project Officer on/before the completion date of the contract; and

f. transfer all hard copy files in an organized manner, providing clear documentation of contents, date of origin, and purpose as specified by the TACC CT and NIAID Project Officer, to a location specified by the TACC CT and NIAID Project Officer on/before the completion date of the contract.

g. Notwithstanding the potential transfer of this project at its conclusion to a successor contractor or to the Government, the Contractor shall maintain full operational capacity until the completion date of the contract.

[END OF STATEMENT OF WORK]

REPORTING REQUIREMENTS

Scientific and Technical Reports

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with ARTICLE F.1. DELIVERIES of this contract:

The Contractor shall submit to the NIAID Contracting Officer and to the Project Officer technical and scientific progress reports covering the work accomplished during each Semi-annual reporting period. In addition, the Contractor shall submit an Annual Automated Information System Security Report. These reports shall be factual and prepared in accordance with the format specified below.

1. Semiannual Scientific and Statistical Report

This report shall summarize the results during the reporting period, and shall be in sufficient detail to explain comprehensively the results achieved. The initial report will be submitted for the first full six months of the contract performance including any fractional part of the initial month. Thereafter, the reporting period shall consist of six full calendar months.

The first report shall be due _____. Thereafter, reports shall be due on or before the 30th of the month following each reporting period.

The original of this report shall be provided to the Contracting Officer, one copy to the Project Officer and one copy to the TACC Coordinating Team (CT). A Semi-annual Report is not required for the period when the Final Report is due.

The report shall summarize the status of the following Consortium activities, including:

a) Statistical Design Considerations

1) Summary of proposed clinical concepts, publications, and status of ongoing analyses. This shall include: Title, author(s), brief description and status of approved analyses, including any pending issues, problems or modifications; and recommendations;

2) The advantages and disadvantages of the various approaches to the statistical design of proposed concepts and manuscripts; and

3) Recommendations for improved statistical approaches and methods to enhance the ability to assess disease stage and activity, therapeutic effect and underlying mechanisms.

b) Scientific Results and Publications, including:

1) Listing of studies initiated, ongoing, and completed in the previous six month period;

2) Summary of interim and final analyses performed;

3) Presentations of study progress and results given at local, national, and international scientific meetings, including electronic files of slide presentations used; and

4) Listing and reprints/preprints of all published/submitted abstracts and manuscripts.

c) Standard Operating Procedures, including:

1) Development, review and implementation of protocol(s), including criteria for evaluation and prioritization;

2) Preparation, review and approval of requests for statistical analyses;

3) Review and approval of publications, abstracts, reports and presentations; and

4) Developing other policies and procedures in conjunction with the TACC CT.

d) Clinical Site Training, including:

1) A summary of issues or problems encountered with respect to the staff training, decision-making processes, including recommendations for modifications and improvements to enhance the timeliness, efficiency or thoroughness of study conduct; and

2) All reports from clinical site visits, including documentation of site capabilities and deficiencies and remedies implemented to assure the sites are in compliance with all appropriate study procedures.

2. Annual Automated Information System Security Report

The Contractor shall provide an Annual Automated Information System Security Report including the Automated Information System (AIS) Security Profile which, at a minimum, shall include:

- System's Security Plan (SSP);
- Risk Analysis (RA);
- Continuity of Operations Plan (COOP also known as the Contingency Plan); and
- Progress on adaptation of the study management data to conform to the Division of AIDS Enterprise System (DAIDS-ES).

The first report shall cover the period_____ through _____ of this contract and shall be due on/before _____ _____. Thereafter, reports shall be due on or before the 30th of the month following each anniversary date of the contract. This report is not required for the period when the Final Report is due.

3. Final Technical Report and Summary of Salient Results

The Final Technical Report shall summarize all Contractor activities for the life of the contract and all final study results and interim results from unfinished studies or analyses and shall be due on/before the completion date of the contract. All study reports shall include the enrollment and retention statistics by clinical site. The Contractor shall submit, with the Final Report, a summary (not to exceed 200 words) of salient results detailing the important accomplishments achieved during the performance of the contract.

4. Other Deliverables

On/before the completion date of the contract, the Contractor shall deliver to the Government the following items:

a) A cleaned and edited public use data set, as specified in SOW, paragraph 10, "Final Transition of Data and Documentation"; and per specifications for the DAIDS-ES;

b) An audit trail of all raw data corrections and data transfers, and all logs and other records related to data validation, editing, analysis - including all well-documented SAS -compatible analytic statistical programs.

5. **Technical Report Distribution**

Item	Deliverable	Quantity	Due Date
1.	Semiannual Status and Statistical Report	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O. 1 Copy – TACC CT	1st Report due on/before _____; thereafter, due on/before the 30th of the month following each reporting period. Not due when Final is due.
2.	Annual Automated Information System Security Report	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	1st Report due on/before _____; thereafter, due on/before the 30th of the month following each anniversary date of the contract. Not due when Final is due.
3.	Final Technical Report and Summary of Salient Results	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	Due on/before the completion date of the contract.
4.	Clean/edited public use data set (see paragraph 4.a), above).	Project Officer	On/before the completion date of the contract.
5.	Computer programs for reading and manipulating data, and creating SAS compatible files.	Project Officer	On/before the completion date of the contract.
6.	Audit Trail of all raw data corrections, hard copies, etc. (see paragraph 4.b), above).	Project Officer	On/before the completion date of the contract.

6. Addressees

Project Officer
BSP, DAIDS, NIAID
6700-B Rockledge Drive, Room ____
MSC 7626
Bethesda, MD 20892-7626

Contracting Officer
CMP, DEA, NIAID
6700-B Rockledge Drive, Room 3214
MSC 7612
Bethesda, MD 20892-7612

PART I - THE SCHEDULE

SECTIONS B - H -- UNIFORM CONTRACT FORMAT - GENERAL

A Sample Uniform Contract Format may be found at the following website:

http://rcb.cancer.gov/rcb-internet/wkf/sample-contract.htm

PART II – CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING PAGES CONTAIN A LISTING(S) OF GENERAL CLAUSES WHICH WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSES LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP.

ARTICLE I.1. GENERAL CLAUSES

The complete listing of these clauses may be accessed at: http://rcb.cancer.gov/rcb-internet/clauses/clauses.html

The following General Clause Listings will be applicable to most contracts resulting from this RFP. However, the organizational structure of the successful offeror(s) will determine the specific General Clause Listing to be contained in the contract(s) awarded from this RFP:

General Clauses for a Cost-Reimbursement Research and Development Contract

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

ITEM 9: **Alternate II** (OCTOBER 2001) of FAR Clause **52.219-9, Small Business Subcontracting Plan** (OCTOBER 2001) is added.

ITEM 13: FAR Clause **52.232-20, Limitation of Cost**, is deleted in its entirety and FAR Clause **52.232-22, Limitation of Funds** (APRIL 1984) is substituted therefor. [Note: When this contract is fully funded, FAR Clause **52.232-22, Limitation of Funds** will no longer apply and FAR Clause **52.232-20, Limitation of Cost** will become applicable.]

See **I.2 Authorized Substitutions of Clauses** of SECTION I at http://rcb.cancer.gov/rcb-internet/wkf/sectioni.pdf for the general listing of Authorized Substitutions of Clauses.

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

52.204-8 Annual Representations and Certifications (Jan 2005).

(a)(1) If the clause at 52.204-7, Central Contractor Registration, is included in this solicitation, paragraph (b) of this provision applies. (2) If the clause at 52.204-7 is not included in this solicitation, and the offeror is currently registered in CCR, and has completed the ORCA electronically, the offeror may choose to use paragraph (b) instead of completing the corresponding individual representations and certifications in the solicitation. The offeror shall indicate which option applies by checking one of the following boxes:

[ ] (i) Paragraph (b) applies.
[ ] (ii) Paragraph (b) does not apply and the offeror has completed the individual representations and certifications in the solicitation.

(b) The offeror has completed the annual representations and certifications electronically via the Online Representations and Certifications Application (ORCA) website at http://orca.bpn.gov. After reviewing the ORCA database information, the offeror verifies by submission of the offer that the representations and certifications currently posted electronically have been entered or updated within the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard applicable to the NAICS code referenced for this solicitation), as of the date of this offer and are

incorporated in this offer by reference (see FAR 4.1201); except for the changes identified below [offeror to insert changes, identifying change by clause number, title, date]. These amended representation(s) and/or certification(s) are also incorporated in this offer and are current, accurate, and complete as of the date of this offer.

FAR Clause #	Title	Date	Change
_____	_____	_____	_____

Any changes provided by the offeror are applicable to this solicitation only, and do not result in an update to the representations and certifications posted on ORCA.

(End of provision)

ITEM 39: FAR Clause **52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns** (JUNE 2003), is applicable to this solicitation.

ITEM 50: FAR Clause **52.227-14, Rights in Data--General** (JUNE 1987).

See **I.3 Additional Contract Clauses of** SECTION I at http://rcb.cancer.gov/rcb-internet/wkf/sectioni.pdf for the general listing of Additional Contract Clauses.

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT:

See **I.4. Additional FAR Contract Clauses Included in Full Text** of SECTION I at http://rcb.cancer.gov/rcb-internet/wkf/sectioni.pdf for the general listing of Additional FAR Contract Clauses Included in Full Text.

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following Attachments are provided in full text with this Solicitation:

PACKAGING AND DELIVERY OF PROPOSALS

HOW TO PREPARE AN ELECTRONIC PROPOSAL

PROPOSAL INTENT RESPONSE SHEET [SUBMIT ON/BEFORE: March 15, 2005]

[NOTE: Your attention is directed to the "Proposal Intent Response Sheet". If you intend to submit a proposal, you must complete this form and return it to this office via fax or e-mail on or before the date identified above. The receipt of this form is critical as it contains information essential for CMP's coordination of the electronic submission and review of proposals.]

RFP FORMS AND ATTACHMENTS:

THE RFP FORMS/ATTACHMENTS LISTED BELOW ARE AVAILABLE IN A VARIETY OF FORMATS AND MAY BE VIEWED OR DOWNLOADED DIRECTLY FROM THIS SITE:

http://www.niaid.nih.gov/contract/ref.htm

APPLICABLE TO TECHNICAL PROPOSAL (INCLUDE THESE DOCUMENTS/FORMS WITH YOUR TECHNICAL PROPOSAL):

- **Technical Proposal Cover Sheet**
- **NIH-1688-1, Project Objectives**
- **Technical Proposal Cost Information**
- **Summary of Related Activities**
- **Optional Form 310, Protection of Human Subjects Assurance Identification/Certification/Declaration** [When applicable, all institutions must have the form reviewed and approved by their Institutional Review Committee.]
- **Government Notice for Handling Proposals**
- **Targeted/Planned Enrollment Table**
- **Information Technology Systems Security - Prospective Offeror Non-Disclosure Agreement**

APPLICABLE TO BUSINESS PROPOSAL (INCLUDE WITH YOUR BUSINESS PROPOSAL):

- **NIH-2043, Proposal Summary and Data Record**
- **Small Business Subcontracting Plan Format (must be submitted with your original Business Proposal)**
- **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours**
- **Offeror's Points of Contact**

TO BECOME CONTRACT ATTACHMENTS (INFORMATION ONLY):

- **Inclusion Enrollment Report**
- **NIH(RC)-4: Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts**
- **NIH(RC)-7: Procurement of Certain Equipment, (OMB Bulletin 81-16)**
- **Safety and Health, HHSAR Clause 352.223-70**
- **Privacy Act System of Records**
- **Report of Government Owned, Contractor Held Property**
- **Government Property – Schedule ___**
- **Disclosure of Lobbying Activities, OMB Form LLL**

PACKAGING/DELIVERY/ELECTRONIC SUBMISSION OF THE PROPOSAL

Please refer to http://www.niaid.nih.gov/contract/eproposal.htm for delivery instructions for the submission of both PAPER and ELECTRONIC COPIES of your proposal.

PAPER SUBMISSION: The paper copy is the official copy for recording timely receipt of proposals.

ELECTRONIC SUBMISSION: In addition to the paper submission, you are requested to submit your proposal electronically through the CRON (Contracts Review Online) in accordance with the instructions provided at the above-referenced weblink. You must certify that both the original paper and electronic versions of the proposal are identical.

The electronic submission is solely for the benefit of the Agency. Such submission is still in a "test" stage, and the electronic submissions may or may not be utilized, at the sole discretion of the Agency.

SUBMISSION OF PROPOSALS BY FACSIMILE IS NOT ACCEPTABLE. -- SUBMISSION OF ONLY ELECTRONIC PROPOSALS WITHOUT PAPER COPIES IS NOT ACCEPTABLE.

WARNING: You are advised to read and carefully follow the instructions listed in this RFP. Failure to adhere to these instructions and to the specified limitations for size of paper and electronic proposals may result in the rejection of your proposal.

NUMBER OF COPIES:

Document	Number of Copies	Page Limits	File Size
Technical Proposal	One (1) unbound SIGNED ORIGINAL. One (1) unbound COPY Twenty (20) bound copies.	Limited to not-to-exceed **150 pages**.	Limited to not-to-exceed 5 mega-bytes
Technical Proposal Appendices All materials not available electronically (i.e. SOPs, Pertinent Manuals, Nonscannable Figures or Data, and Letters of Collaboration/Intent).	One (1) unbound SIGNED ORIGINAL. One (1) unbound COPY Twenty (20) bound copies.	This information is included in the total page limitation of 150 pages.	N/A
Business Proposal	One (1) unbound SIGNED ORIGINAL. One (1) unbound COPY Ten (10) bound copies.	Limited to not-to-exceed 150 pages	Limited to not-to-exceed 5 mega-bytes
Representations and Certifications	Provide representations and certifications electronically via the BPN website (www.bpn.gov/orca)	N/A	N/A
All offerors are required to submit three (3) CDs that contain electronic versions of all proposal information (both technical and business – clearly marked). If information appended to the paper version is not available electronically, the CD shall contain a file listing all documents that are submitted in paper format only. **The offeror shall include certification that the documents provided electronically match the paper version of those same documents.**		Technical Proposal: 2 Compact Discs (CDs) Business Proposal: 1 Compact Disc (CD)	

TECHNICAL PROPOSAL PAGE LIMITS INCLUDE: Appendices, Attachments, Operating Manuals, Non-Scannable Figures or Data, Letters of Intent, etc..

TOTAL PAGE COUNT DOES NOT INCLUDE: 1 Cover and Back Page; 1 Table of Contents; Section Dividers that do not contain information other than title of Section.

ANY PORTIONS OF YOUR PROPOSAL NOT AVAILABLE ELECTRONICALLY ARE ALSO CONSIDERED TO BE INCLUDED IN THE TOTAL PAGE LIMITATION.

PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE PROVIDED TO THE REVIEWERS TO BE READ OR EVALUATED.

HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL

ELECTRONIC SUBMISSION – To submit a proposal electronically under this RFP, offerors will need to prepare the proposal on a word processor or spreadsheet program (for the business portion) and convert them to Adobe Acrobat Portable Document Format (.pdf). THE TECHNICAL PROPOSAL AND BUSINESS PROPOSAL MUST BE CONTAINED ON SEPARATE FILES which must be identified as either TECHNICAL or BUSINESS and include some recognizable portion of the ORGANIZATION NAME.

Please note that the electronic submission does not replace the requirement to submit a signed, unbound original paper copy of both your Technical and Business Proposal, along with any required unbound duplicate copies. These paper originals should be mailed or hand-delivered to the address provided in Box 18 of the RFP cover page and must be received on/before the closing date and time.

For purposes of assessing compliance with the page count, technical proposals will be viewed using the print function of the Adobe Acrobat Reader, Version 4.0 (or higher).

Formatting Requirements:

- Do not embed sound or video (e.g., MPEG) files into the proposal documents. The evaluation system does not have the capability to read these files.
- Documents must be converted to a .pdf searchable format.
- Keep graphics embedded in documents as simple as possible. Complex graphics require longer periods for the computers used in the evaluation system to draw, and redraw these figures and scrolling through the document is slowed significantly.
- Type density and size must be 10 to 12 points. If constant spacing is used, there should be no more than 15 cpi, whereas proportional spacing should provide an average of no more than 15 cpi. There must be no more than six lines of text within a vertical inch. Margins must be set to 1 inch around.
- Paper size should not exceed 8-1/2 x 11. Larger paper sizes will be counted as 2 pages.
- Limit colors to 256 colors at 1024 x 768 resolution; avoid color gradients.
- Simplify the color palette used in creating figures.
- Be aware of how large these graphics files become. Large files are discouraged.
- Pages printed front-to-back will count as 2 pages.
- Pages may not be printed in column format.
- Limit scanned images as much as possible.
- Limit appendices and attachments to relevant technical proposal information (e.g., SOPs, pertinent manuals, non-scannable figures or data, resumes, letters of commitment/intent).

SUBMISSION OF "PROPOSAL INTENT RESPONSE SHEET":

Upon receipt by the Contracting Officer of the "Proposal Intent Response Sheet", offerors will be provided, via e-mail correspondence, specific electronic access information and electronic proposal transmission instructions. For this reason, it is imperative that all offerors who are intending to submit a proposal in response to this RFP contact the Contract Specialist identified in this RFP and complete and submit the attached "Proposal Intent Response Sheet" by the date provided on that Attachment.

CREATE ADOBE PDF ONLINE -- Adobe will allow you to create 5 documents on a trial for free. If you want to use the site regularly it costs $10/month or $100/year. Please link to the following URL for information:

https://createpdf.adobe.com/index.pl/3847995518.39272?BP=IE

LOG-IN / TRANSMISSION INSTRUCTIONS:

1. Log-in Site: Will be provided by the Contract Specialist after receipt of the"Proposal Intent Response Sheet"
2. Log-in Name: Will be provided by the Contract Specialist via e-mail.
3. Log-in Password: Will be provided by the Contract Specialist via e-mail.
4. Procedure: When your proposal is completed and converted to a PDF file using Adobe Acrobat, it is ready to be transmitted electronically. You must upload separate Technical and Business Proposal Files. It is recommended that proposals be transmitted a few days before the due date so that you will have sufficient time to overcome any transmission difficulties.

   - You must have Explorer 3.1 or higher.
   - It is essential that you use antiviral software to scan all documents.
   - Click on "Sign On" and enter your log-in name and password.
   - Click on "Browse" to locate your saved files on your computer.
   - Click on "Upload Proposal" after you have located the correct file.
   - After a file is uploaded, a link to the file will appear under "Upload Files" at the bottom of the screen. Click on that link to view the uploaded file.
   - If you experience difficulty in accessing your documents, please contact the appropriate NIH contracts office immediately.
   - If you wish to revise your proposal before the closing date and time, simply log in again and re-post.

USER ACCESS TO THE POSTING SITE WILL BE DENIED AFTER THE RFP CLOSING DATE AND TIME PROVIDED WITH THIS RFP OR ITS MOST RECENT AMENDMENT(S).

PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DAIDS-06-06
RFP Title: "Tri-Service AIDS Clinical Consortium Data Analysis and Coordinating Center (TACC/DACC)"

Please review the attached Request for Proposal. Furnish the information requested below and return this page by March 15, 2005. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

Since your proposal will also be submitted electronically, please include the name and e-mail of the individual to whom the electronic proposal instructions, login code, and password should be provided.

[ ] DO INTEND TO SUBMIT A PROPOSAL
[ ] DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

Company/Institution Name (print): _____
Address (print): _____
_____
_____
_____

Project Director's Name (print): _____
Title (print): _____
Signature/Date: _____
Telephone Number and E-mail Address (print clearly):
_____
_____

***Name of individual to whom electronic proposal instructions should be sent:**

Name: _____
Title: _____
E-Mail Address: _____
Telephone Number: _____

Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants) (print):

_____
_____
_____
_____
(Continue list on a separate page if necessary)

RETURN VIA FAX OR E-MAIL TO:
CMP, NIAID, NIH
Room 3214
6700-B Rockledge Drive, MSC 7612
Bethesda, MD 20892-7612
Attn: Barbara Shadrick
RFP-NIH-NIAID-DAIDS-06-06
FAX# (301) 402-0972
Email : bs92y@nih.gov

PART IV – REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

Representations, Certifications, and Other Statements of Offerors or Quoters (Negotiated).

1. REPRESENTATIONS AND CERTIFICATIONS

Federal Acquisition Circular (FAC 2001-26), published on December 20, 2004, implements the ***Online Representations and Certifications Application (ORCA)*** effective on January 1, 2005. The ORCA became a Federal mandate as published in the Federal Acquisition Circular 2001-26, FAR case 2002-024, and now requires the use of ORCA in Federal solicitations as a part of the proposal submission process.

ORCA is part of the Business Partner Network (BPN) which is a component of the Integrated Acquisition Environment (IAE) E-Gov initiative. It is a web-based system that centralizes and standardizes the collection, storage and viewing of many of the FAR required representations and certifications previously found in solicitations. With ORCA, you now have the ability to enter and maintain your representation and certification information, at your convenience, via the Internet at http://orca.bpn.gov. In addition, rather than receiving and reviewing paper submissions, government contracting officials can access ORCA and review your information online as a part of the proposal evaluation process. You will no longer be required to submit representations and certifications completed in ORCA with each offer.

The final rule requires offerors to: (a) provide representations and certifications electronically via the BPN website (www.bpn.gov/orca) thus reducing the administrative burden on vendors who have been submitting the same reps and certs repeatedly for various solicitations, (b) to maintain the representations and certifications at least annually so they stay current, (c) to make changes that affect only one solicitation by completing sections of specific provisions that are required by the FAR, included in the solicitation. This will result in a reduced paperwork burden for both offerors and contracting officers thus fulfilling one of the goals of IAE to re-use data as much as possible throughout the Federal procurement life cycle.

To comply with this requirement and to register in ORCA, you will need to have two items: an active Central Contractor Registration (CCR) record and a Marketing Partner Identification Number (MPIN) identified in that CCR record. Your DUNS number and MPIN act as your company's ID and password into ORCA. (Visit www.ccr.gov for more information on creating and entering your MPIN). The basic information provided in your CCR record is used to pre-populate a number of fields in ORCA. Vendors are reminded to protect their MPIN from unauthorized use. Once in ORCA you will be asked to review pertinent information pre-populated from CCR, provide a point of contact, and answer a questionnaire that contains up to 26 questions. The questionnaire is to help you gather information you need for the clauses. The questionnaire is not the official version. Be sure to read the provisions carefully.

The answers you provide are then automatically entered into the actual FAR provisions. You are required to review your information, as inserted, in context of the full-text provisions for accuracy; acknowledge three additional read-only provisions; and click a time/date stamp before final submission. You will need to review and/or update your ORCA record when necessary, but at least annually in order to maintain its active status. Detailed information regarding ORCA, how to submit your record, and whom to call for assistance can be found on ORCA's homepage at http://orca.bpn.gov under "Help." The ORCA site contains an ORCA Application Handbook and an ORCA Quick Reference Guide. To access them, simply click on the "Help" link at the top of the ORCA homepage.

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLY WITH THE ABOVE REQUIREMENT.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

The following information is specific to this solicitation and is provided to supplement and/or complete the associated ITEMS presented at the SECTION L website at http://rcb.cancer.gov/rcb-internet/wkf/sectionl.pdf

I. GENERAL INFORMATION

ITEM 2: **Alternate I, of FAR Clause 52.215-1, INSTRUCTIONS TO OFFERORS-COMPETITIVE ACQUISTION,** is applicable to this solicitation.

ITEM 9: **NAICS CODE AND SIZE STANDARD**

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, **SMALL BUSINESS PROGRAM REPRESENTATION,** FAR Clause 52.219-1.

(1) The NAICS Code is 541710.
(2) The small business size standard is 500 employees.

ITEM 10: **THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS.** However, the Federal Acquisition Regulation (FAR) requires in every solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

ITEM 11: In accordance with FAR Clause 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns, incorporated in Section I.3., offerors will be evaluated by adding a factor of *[percentage to be identified in the specific RFP]* percent to the price of all offers, except offers from small disadvantaged business concerns that have not waived the adjustment. (Note: A listing of other offerors who are excepted and will not have this evaluation factor added to their offer may be found in subparagraph (b) of FAR Clause 52.219-23.

A small disadvantaged business concern may elect to waive the adjustment, in which case the factor will be added to its offer for evaluation purposes. The agreements in paragraph (d) of FAR Clause 52.219-23 do not apply to offerors that waive the adjustment.

AN OFFEROR WHO ELECTS TO WAIVE THIS EVALUATION ADJUSTMENT MUST SPECIFICALLY INDICATE WITH A STATEMENT TO THIS EFFECT ON THE COVER PAGE OF ITS BUSINESS PROPOSAL.

ITEM 12: **TYPE OF CONTRACT AND NUMBER OF AWARD(S)**

It is anticipated that one award will be made from this solicitation and that the award will be made on/about December 15, 2005.

It is anticipated that the award(s) from this solicitation will be a multiple-year, cost-reimbursement, completion type contract, with a period of performance of five (5) years, and that incremental funding will be used [see Section L, PART IV - Business Proposal Instructions].

ITEM 14: **ESTIMATE OF EFFORT**

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 9.5 full time equivalents (FTEs). This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

ITEM 17: COMPARATIVE IMPORTANCE OF PROPOSALS

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors is specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

ITEM 20: SERVICE OF PROTEST (AUGUST 1996) - FAR 52.233-2

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (*Complete address and contact information can be found on the SECTION A SOLICITATION/CONTRACT FORM cover page, Blocks 9 & 15, of the specific RFP*) by obtaining written and dated acknowledgment of receipt from:

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

ITEM 21: LATE PROPOSALS AND REVISIONS, HHSAR 352.215-70, is applicable to this solicitation.

II. GENERAL INSTRUCTIONS

ITEM 24: Potential Award Without Discussions, is applicable to this solicitation.

ITEM 30: Sharing Research Data, is applicable to this solicitation.

ITEM 32: Specific Copyright Provisions Applicable to Software Development and/or Enhancements, is applicable to this solicitation.

ITEM 34: Small Business Subcontracting Plan, is applicable to this solicitation and the following information is provided to supplement this item to assist in proposal preparation. **A Subcontracting Plan must be submitted with the original proposal and will be subject to negotiations if your proposal is determined to be in the competitive range.** The anticipated minimum subcontracting goals for this RFP are as follows:

- 23% for Small Business
- 5% for Small Disadvantaged Business
- 3% for Women-Owned Small Business
- 5% for HUBZone Small Business
- 3% for Veteran-Owned Small Business
- 3% Service-Disabled Veteran-Owned Small Business.

ITEM 36: Extent of Small Disadvantaged Business Participation, is applicable to this solicitation.

ITEM 37: Salary Rate Limitation in Fiscal Year 2005, will be applicable to this solicitation.

ITEM 40: Past Performance Information is applicable to this solicitation and the following information is provided to supplement this item to assist in proposal preparation:

Past Performance information shall be submitted as part of the **Business** proposal.

A list of the last three (3) contracts completed during the past three years and the last three (3) contracts awarded currently in process that are similar in nature to the solicitation workscope.

ITEM 48: Electronic and Information Technology Accessibility, is applicable to this solicitation.

ITEM 49: **Prohibition on Contractor Involvement with Terrorist Activities**, is applicable to this solicitation.

ITEM 50: **Solicitation Provisions Incorporated by Reference:** The following provisions are applicable to this solicitation.

Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).

Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).

Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

III. TECHNICAL PROPOSAL INSTRUCTIONS

ITEM 52: **Project Objectives, NIH-1688-1, is** applicable to this solicitation.

ITEM 54: **Human Subjects**, is applicable to this solicitation.

ITEM 55: **Information Technology Systems Security**, is applicable to this solicitation.

IV. BUSINESS PROPOSAL INSTRUCTIONS

ITEM 57: **Proposal Cover Sheet,** is applicable to this solicitation.

ITEM 60: **Cost and Pricing Data** is applicable to this solicitation.

Subparagraph 3. Formats for Submission of Line Item Summaries:

[x] The format specified in SECTION L at http://rcb.cancer.gov/rcb-internet/wkf/sectionl.pdf is applicable to this solicitation.

ITEM 61: **Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data [FAR Clause 52.215-20 (October 1997)],** is applicable to this solicitation.

ITEM 66: **Incremental Funding,** is applicable to this solicitation.

SECTION M - EVALUATION FACTORS FOR AWARD

1. **GENERAL**

Selection of an offeror for contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: technical, cost/price, past performance and Small Disadvantaged Business (SDB) Participation. Although technical factors are of paramount consideration in the award of the contract, cost/price, past performance and SDB Participation are also important to the overall contract award decision. All evaluation factors other than cost/price, when combined, are significantly more important than cost or price. The trade-off process described in FAR 15.101-1 may be employed. This process permits tradeoffs among cost/price and non-cost factors and allows the Government to consider award to other than the lowest priced or highest technically rated offeror. In any event, the Government reserves the right to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

2. **HUMAN SUBJECT EVALUATION**

This research project may involve human subjects. NIH Policy requires:

(a) **Protection of Human Subjects from Research Risks**

The offeror's proposal must address the involvement of human subjects and protections from research risk relating to their participation, or provide sufficient information on the research subjects to allow a determination by Institute that a designated exemption is appropriate.

If you claim that this research should be considered exempt from coverage by the Federal Regulations at 45 CFR 46, the proposal should address why you believe it is exempt, and under which exemption it applies.

The reviewers will evaluate the proposal and provide a narrative with regard to four issues: Risks to Human Subjects, Adequacy of Protection Against Risks, Potential Benefits of the Proposed Research to the Subjects and Others, and Importance of the Knowledge to be Gained. See Section L for a complete discussion of what is required to be addressed for each of these issues. Based on the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the protections described against risk to human subjects or no discussion is found regarding protections against risk to human subjects) or "acceptable".

If your discussion regarding the protection of human subjects from research risks is rated "unacceptable" and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss and/or clarify your position during such discussions and in your Final Proposal Revision (FPR). If, after discussions, your proposed plan for the protection of human subjects from research risks is still found unacceptable, your proposal may not be considered further for award.

(b) **Data and Safety Monitoring**

The offeror's proposal must include a general description of the Data and Safety Monitoring Plan for all clinical trials. The principles of data and safety monitoring require that all biomedical and behavioral clinical trails be monitored to ensure the safe and effective conduct of human subjects research, and to recommend conclusion of the trial when significant benefits or risks are identified or if it is unlikely that the trial can be concluded successfully. Risks associated with participation in research must be minimized to the extent practical and the method and degree of monitoring should be commensurate with risk. Additionally, all plans must include procedures for adverse event reporting. Finally, generally, for Phase III clinical trials, the establishment of a Data and Safety Monitoring Board (DSMB) is required, whereas for Phase I and II clinical trials, the establishment of a DSMB is optional. The reviewers should refer to the Statement of Work and Section L in the solicitation, as well as any further technical evaluation criteria in this Section M, as applicable, for the solicitations specific requirements for data and safety monitoring.

As a part of the evaluation for proposals, the reviewers will provide a narrative that describes the acceptability of the proposed data and safety monitoring plan with respect to the potential risks to human participants, complexity of study design, and methods for data analysis. Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the adequacy of the monitoring plan or no discussion can be found regarding the proposed monitoring plans) or "acceptable."

If the information provided regarding Data and Safety Monitoring is rated "unacceptable" and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss and/or clarify your plan during such discussions and in your Final Proposal Revision (FPR). If, after discussions, the plan is still considered "unacceptable," your proposal may not be considered further for award.

(c) **Women and Minorities**

Women and members of minority groups and their subpopulations must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. In addition, for NIH-Defined Phase III clinical trials, all proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, Definitions - Significant Difference) by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable, unless the Government has specified that this solicitation involves a sex/gender specific study or a single or limited number of minority population groups. The proposal also must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, OR

- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups (representation of sex/gender and/or racial/ethnic groups as subject selection criterion is not required; however, inclusion and analyses are encouraged), OR

- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Also, the proposal must address the proposed outreach programs for recruiting women and minorities as participants.

Reviewers will address the areas covered here and in Section L of the solicitation in narrative form in their evaluation. Some of the issues they will evaluate include:

- whether the plan proposed includes minorities and both genders in adequate representation
- how the offeror addresses the inclusion of women and members of minority groups and their subpopulations in the development of a proposal that is appropriate to the scientific objectives of the solicitation
- the description of the proposed study populations in terms of sex/gender and racial/ethnic groups and the rationale for selection of such subjects
- if exclusion is proposed, that the rationale is appropriate with respect to the health of the subjects and/or to the purpose of the research.
- In addition, for gender exclusion, the reviewers will examine the rationale to determine if it is because:
  - the purpose of the research constrains the offeror's selection of study participants by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or
  - overriding factors dictate selection of subjects); or
  - gender representation of specimens or existing datasets cannot be accurately determined, and this does not compromise the scientific objectives of the research.

- For minority group exclusion, the reviewers will examine the rationale to determine if those minority groups are excluded because:
  - inclusion of those groups would be inappropriate with respect to their health,;or
  - inclusion of those groups would be inappropriate with respect to the purpose of the research.
- For NIH-defined Phase III clinical trials, reviewers will also address whether there is an adequate description of plans to conduct analyses to detect significant differences of clinical or public health importance in intervention effect(s) by sex/gender and/or racial ethnic subgroups when the intervention effect(s) is expected in the primary analyses, or if there is an adequate description of plans to conduct valid analyses of the intervention effect in subgroups when the intervention effect(s) is not expected in the primary analyses.

If you determine that inclusion of women and minority populations is not feasible, you must submit a detailed rationale and justification for exclusion of one or both groups from the study population with the technical proposal. The Government will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research

Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed gender/minority inclusion plans, or concerns are identified as to the gender or minority representation, or the proposal does not adequately address limited representation of one gender or minority; or the plan is not in accordance with NIH policy guidelines) or "acceptable." See Section L of the solicitation for the requirements of women/minorities inclusion.

If the information you provide in your proposal regarding the inclusion of women and minorities is rated "unacceptable" and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify, or modify your plan during discussions and in your Final Proposal Revision (FPR). If your plan for inclusion/exclusion of women/minorities is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.

(d) **Children**

Children (i.e. individuals under the age of 21) must be included in all human subject research unless there are clear and compelling reasons not to include them.
Your proposal must include a description of plans for including children. If you plan to exclude children from the required research, your proposal must present an acceptable justification for the exclusion. If you determine that exclusion of a specific age range of child is appropriate, your proposal must also address the rationale for such exclusion. Also, the plan must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation. Also, see Section L of the solicitation for further specific requirements on inclusion of children.

Based on the reviewers' narrative evaluation of the offeror's response to this evaluation criterion, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed inclusion plans for children; or concerns are identified as to the offeror's response regarding the inclusion of children; or the plan is not in accordance wit h NIH policy guidelines) or "acceptable."

If the information provided in your proposal about the inclusion of children is rated "unacceptable" and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify your plan during discussions and in your Final Proposal Revision (FPR). If your plan for inclusion of children is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.

3. EVALUATION OF DATA SHARING PLAN

The offeror's plan for the sharing of final research data shall be assessed for appropriateness and adequacy.

If your proposal does not include a plan or if the plan in your proposal is considered "unacceptable," and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify your data sharing plan during discussions and in your Final Proposal Revision (FPR). If your data sharing plan is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.

4. PAST PERFORMANCE FACTOR

An evaluation of offerors' past performance information will be conducted prior to any communications with offerors leading to establishment of the competitive range. However, this evaluation will not be conducted on any offeror whose proposal will not be admitted to the competitive range on the basis of the results of the evaluation of factors other than past performance.

The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

The assessment of performance risk is not intended to be a product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers relevant information.

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

5. **EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION**

SDB participation will not be scored, but the Government's conclusions about overall commitment and realism of the offeror's SDB Participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

(a) Extent of commitment to use SDB concerns
(b) Realism of the proposal
(c) Extent of participation of SDB concerns in terms of the value of the total acquisition.

6. TECHNICAL EVALUATION CRITERIA

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

CRITERIA **WEIGHT**

A. TECHNICAL APPROACH **40 Points**

1. Demonstrated understanding of the scope and objectives of the contract as evidenced by the soundness and practicality of the technical approach.

   Executing the requirements specified in the Statement of Work, with adequate explanation, substantiation and justification for the proposed methods for meeting the projected needs, including:

   a. statistical design and analysis, including the capacity to develop and apply innovative epidemiologic and statistical methods in longitudinal data analyses;
   b. establishing and administering reliable, efficient and responsive data management, validation, and quality assurance systems;
   c. designing and implementing clinical site training requirements and evaluations;
   d. supporting the development and writing of protocols for retrospective and prospective clinical studies;
   e. distribution and quality control of study instruments; and
   f. statistical, technical, administrative and logistical support for the activities of the TACC.

B. QUALIFICATIONS, EXPERIENCE AND AVAILABILITY OF PERSONNEL **30 Points**

1. Principal Investigator/Co-Investigators including:

   a. documented availability, training, qualifications, expertise, relevant experience, education, and leadership/management skills of the Principal Investigator and the co-investigators to successfully plan and manage the project;
   b. expertise in longitudinal cohort-specific study design;
   c. expertise in the implementation and monitoring of longitudinal data and clinical site training; and
   d. managerial ability to achieve delivery or performance requirements, drawing upon the resources of the primary contractor, and subcontractors/consultants as necessary.

2. Other Personnel

   a. documented availability, training, qualifications, expertise, relevant experience, education and competence of the scientific, clinical, technical and administrative staff and any other proposed personnel [including proposed subcontractors and consultants], to perform the requirements of the Statement of Work; and
   b. expertise in the successful development and implementation of computerized databases and laboratory data management systems.

C. EXPERIENCE AND CAPABILITIES OF THE ORGANIZATION **20 Points**

1. documented relevant experience of the organization in managing projects of similar complexity and scope and in managing multiple subcontracts and/or consultants;
2. clarity and appropriateness of lines of communication and authority for coordination and management of the project;

3. adequacy and feasibility of plans to ensure successful coordination of a multi-organizational collaboration; and
4. ability to identify and procure ad-hoc clinical and scientific consultants to address the evolving science of HIV infection.

D. FACILITIES AND RESOURCES **10 Points**

Documented availability and adequacy of facilities, equipment, space and resources, including shared resources and those of proposed subcontractor(s), necessary to carry out the Statement of Work, including:

1. location and features of locked, fire-protected storage for hard copies of study files and documents;
2. hardware and software specifications for proposed electronic data management and web-based systems;
3. data storage and maintenance capabilities and establishment of security systems to insure confidentiality and protection of data;
4. graphics capabilities; and
5. telecommunications and conferencing capabilities.

TOTAL = 100 Points

APPENDIX A - ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS
FORMAT FOR TECHNICAL PROPOSAL – TABLE OF CONTENTS

THE BELOW TEMPLATE SHALL BE USED AS THE TABLE OF CONTENTS FOR YOUR TECHNICAL PROPOSAL, AND ALL INFORMATION IN YOUR TECHNICAL PROPOSAL SHOULD BE PRESENTED IN THE ORDER SPECIFIED BELOW.

YOU ARE REMINDED THAT THE TOTAL PAGE LIMITATION FOR THE ENTIRE TECHNICAL PROPOSAL PACKAGE IS 150 PAGES. PLEASE REFER TO THE FOLLOWING LINK FOR SPECIFIC PROPOSAL PREPARATION INSTRUCTIONS WITH REGARD TO PAGE LIMITATIONS:
http://www.niaid.nih.gov/contract/eproposal.htm#electronic

THESE ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS REFLECT THE REQUIREMENTS OF THE RFP AND ARE MEANT TO PROVIDE A CLEAR UNDERSTANDING OF THE INTENT OF THIS SOLICITATION.

OFFERORS ARE ADVISED TO GIVE CAREFUL CONSIDERATION TO THE STATEMENT OF WORK, ALL REFERENCE MATERIAL PROVIDED AS APPENDICES AND ATTACHMENTS, AND THE TECHNICAL EVALUATION CRITERIA IN THE DEVELOPMENT OF YOUR PROPOSAL.

TECHNICAL PROPOSAL – TABLE OF CONTENTS

General Comment: Offerors may identify tasks, among those described in this solicitation, for which they plan to utilize subcontractors. This approach is encouraged if it allows the offeror to more efficiently perform the numerous responsibilities of the DACC. Offerors should describe the activities to be subcontracted, the method and level of integration between the DACC and any proposed subcontractor(s), and the expected advantages of such an approach.

The **technical proposal may not exceed 150 pages** and should provide specific information addressing the elements listed in the Statement of Work and those specified below.

1. **Collaboration with the TACC study sites and the TACC Coordinating Team (CT)**

   To address the requirement for a collaborative, accountable, and effective management structure, the Technical Proposal shall include:

   a. An organizational chart demonstrating proposed lines of communication between DACC personnel, DAIDS staff, the CT, and Clinical Sites; and

   b. A discussion of how the DACC will interact with DAIDS staff, the CT, TACC investigators, and study site personnel so that these parties may function as a team.

2. **Initial Data Cleaning, Validation, and Quality Assurance Plan and Procedures**

   The Technical Proposal shall include an Initial Data Cleaning, Validation, and Quality Assurance plan and procedures for implementation, that shall discuss the requirements specified in the Statement of Work.

3. **Ongoing Data Validation, Data Cleaning, and Quality Assurance**

   The Technical Proposal shall delineate strategies to establish and administer a data validation system for the collection, tracking, processing, integration, quality assurance, transfer and reporting of study data, as well as a system for electronic communication and collaboration. Data shall be located on a designated multiprocessor server with adequate memory and RAM to support complex data manipulation and graphical applications as well as working directories for data center staff and TACC investigators. The file system structure should provide an efficient means of organizing all components of the data center activities. Statistical software should include the most recent version of Windows for networking, SAS/BASE, SAS/STAT, SAS/GRAPH, SAS/IML, SAS/AF, SAS/FSP, SPlus, and other programming capacity for

processing, storage, retrieval, and multivariable analyses of longitudinal clinical, laboratory, and pharmaceutical data for more than 5,000 observations. The offeror should provide an off-site facility for secure storage of system back-ups.

The Technical Proposal should demonstrate the capacity of the offeror to address Data Management and Ongoing Quality Assurance needs as specified in the Statement of Work.

4. Security Requirements

The Technical Proposal shall include plans to demonstrate compliance with security requirements as specified in the Statement of Work.

5. Cohort Study Support, Training and Communication

The Technical Proposal shall include a feasible plan and demonstrate expertise to fulfill the activities listed in the Statement of Work for Cohort Study Support, Training, and Communication.

6. Consultation in Scientific Design and Analytic Strategies

The Technical Proposal shall demonstrate that the broad range of expertise required can be adequately provided to address statistical approaches and clinical study design features that are important in developing and analyzing observational or interventional clinical studies.

7. Data Analysis for Retrospective, Prospective, and Collaborative Research

The Technical Proposal shall document staff expertise to conduct complex data analyses in support of manuscript preparation including:

a. Knowledge and analytic skills in theoretical statistics, data modeling, repeated measures, and exploratory data analysis using robust methods;

b. Descriptions of previous and current projects of a similar nature, including the grant or contract number, the sponsoring agency, the project officer, and description of the project; and

c. Reprints of all publications or reference list.

8. Clinical Trial Design and Analytic Support

The Technical Proposal shall provide evidence of experience and capability to support the conduct of clinical trials and analyses of data derived therein as evidenced by work accomplished.

9. Medical Reports and Presentations

Offerors shall include in their proposal examples of medical writing, identified by author and by other personnel.

10. Final Transition of Data and Documentation

The Technical Proposal shall include a plan for an audit trail of all data corrections, editing, and analyses, and a final transfer of all TACC DACC data as specified in the Statement of Work.

11. Personnel and Organization Management

With regard to adequate qualified DACC personnel, the Technical Proposal shall include a Staffing Plan for the conduct of the Statement of Work, including role descriptions and level of effort of key scientific, technical and administrative personnel and, plans for back-up scientific, technical and administrative staffing.

a. Key Scientific and Technical Personnel: Describe the experience and qualifications, as well as the percentage of the total time each will be committed to the project. Identify the composition of the task or work group, its general qualifications and recent experience with similar efforts. As a minimum, this effort will require different staff/areas of expertise at different times over the course of the contract. Please provide documentation to describe:

- Key Scientific and Technical Personnel (limit CVs to 2-3 pages) including doctoral level statistical analysts and epidemiologists, and one or more competent scientific writers, data programmers, and web developers;
- Qualifications and relevant training as supported by academic degree(s) and demonstration of previous experience doing similar complex projects;
- References to all publications;
- Availability for the proposed project;
- Summary of Related Activities.

b. Other Personnel: Offeror(s) should discuss the related experience and the role of other personnel as well as the ability to access and secure ad hoc clinical and scientific expertise as needed to address new scientific agendas in HIV infection. Other personnel may include non-key scientific, technical, and administrative personnel. *[NOTE: Actual CVs for Other Personnel should not be included with the Technical Proposal but should be included with the Business Proposal. Although they will not be available for review by the initial peer review panel, they will be reviewed by the NIAID Project Officer and Contracting Officer as part of the analysis for competitive range determination.]*

12. Facilities and Resources

The Technical Proposal shall document availability and adequacy of facilities, equipment, space and other resources necessary to carry out the Statement of Work, including:

a. Location and features of secured storage for hard copies of documents and files;

b. Hardware and software for proposed electronic data management and web-based systems;

c. Graphics capabilities; and

d. Telecommunications and conferencing capabilities.

13. Human Subjects / HIPPA

a. Human Subjects

Include plans for compliance with applicable domestic and international regulations on the use of human subjects (e.g. IRB submission and approval plans, consent procedures, etc.).

b. Health Insurance Portability and Accountability Act (HIPAA)

Include plans for compliance with HIPAA.

c. Privacy Act

Include plans for compliance with the Privacy Act.

14. Past Performance Reference Material

The Technical Proposal should include documentation of past performance demonstrating scientific productivity and expertise as well as managerial ability, relevant experience, and capacity to achieve delivery and performance of requirements specified in the Statement of Work.

15. Data Sharing Plan

The Technical Proposal should include a plan for preparing a public use data archive and a plan for preparing and transferring the DAIDS-ES-compatible required data.

APPENDIX B
ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS
UNIFORM BUDGET ASSUMPTIONS

1. Collaboration with the TACC study sites and the TACC Coordinating Team (CT)

For cost estimating purposes, offerors shall assume the following:

- The TACC DACC shall support travel of its scientific and project management staff to semi-annual meetings with the TACC CT and NIAID. One meeting per year will take place in the Washington, DC area. The second meeting each year will take place on a rotating basis between the TACC study sites and finalized by consensus by the TACC CT, TACC clinical site investigators, the TACC DACC, and the NIAID PO. Meetings will last 2-3 days. Study procedures will be evaluated, progress on the current scientific agenda will be presented and scientific questions to be addressed during the next six months will be jointly determined with the TACC DACC and the TACC site investigators.

- Additional external advisory committee meetings will occur semi-annually and are usually scheduled to follow a large national scientific meeting. The TACC DACC will support travel of key personnel to the advisory committee meetings and other scientific meetings as deemed necessary by the TACC CT, the TACC DACC, and the NIAID PO.

2. Initial Data Cleaning, Validation, and Quality Assurance

For cost estimating purposes, offerors are informed of the following:

- There are seven TACC clinical sites throughout the U.S.
    - Walter Reed Army Medical Center, Washington, D.C.
    - Tripler Army Medical Center, Honolulu, Hawaii
    - Brook Army Medical Center and Wilford Hall Medical Center, San Antonio, Texas
    - National Naval Medical Center, Bethesda, Maryland
    - U.S. Naval Medical Center, San Diego, California
    - Naval Medical Center, Portsmouth, Virginia.

- Approximately 4500 participants have been enrolled in the TACC cohort since 1986. At this time, 36% (n=1597) have unknown outcomes.
- Approximately 125 new participants enroll in the TACC per year.

3. Ongoing Data Validation, Data Cleaning, and Quality Assurance

For cost estimating purposes, offerors are informed of the following:

- HIV-1 Natural History data were derived from the consolidation of three protocols.
- A new protocol is will be implemented in 2005.
- The current data management system includes the following procedures:
    - After each clinic visit, data are abstracted from medical records to complete TACC case report forms. These forms collect information on medical history and current diagnoses, medications, interim visits, hospitalizations, and laboratory results.
    - Case report forms are sent by courier or overnight carrier to the current data center.
    - Data are double entered into the database at the current data center.
- There is no system of quality assurance of the data.
- Pharmacy data and laboratory results may be transferred electronically in the near future.

4. **Cohort Study Support, Training and Communication**

For cost estimating purposes, offerors shall assume the following:

- Site visits for quality assurance evaluations will be conducted at each of the seven sites once per year.
- Changes in study operating procedures or data entry shall require additional days of training at each site or at a central location by agreement.
- Interim site visits may occur more frequently as necessary.